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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,323	03/11/2004	Jessica G. Chiu	5618P3784	1769

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,323	CHIU ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-68 and 79-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-68 and 79-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 61-66, 68, 79-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peacock, III et al. (US 20020049402). Peacock discloses the method substantially as claimed including: advancing a cannula percutaneously through a blood vessel to a region of interest (Figs.1a and 1b), the cannula having a proximal end (near 7), a distal end (near 4), and an exterior surface at or adjacent the distal end of the cannula axially coupled to a balloon (3), inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest (the balloon is inflated via lumen 3'); infusing a treatment agent to the region of interest distal to the balloon during

the occlusion of the blood vessel (delivery ports 8 deliver cardioplegia agent [0071]-[0073] and as can be seen in Fig. 1a, ports 8 are distal to the balloon member 3); perfusing a blood flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon (paragraph [0071] discloses that the blood will enter through ports 4 and exit through ports 5 when internal valve 6 is open and valve 7 is closed, and since the cardioplegia agent is delivered distal to ports 4, the agent will perfuse with the blood in this manner). Peacock, while disclosing that a treatment agent such as cardioplegia may be delivered distal to the balloon and also disclosing that blood may be perfused between the distal and proximal sides of the balloon (see above), does not specifically disclose that during the perfusion between the distal and proximal sides of the balloon a treatment agent is perfused along with the blood. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of Peacock such that the perfusing of blood between the distal and proximal sides of the balloon occurs after the cardioplegia fluid has been delivered such that the cardioplegia fluid would also perfuse with the blood, as Applicant has not claimed the order in which the method steps must be carried out, and perfusion between the two sides of the balloon must eventually occur after delivery of the cardioplegia fluid in order to prevent the tissue from dying. Furthermore, Applicant has not claimed how much time must elapse between the time that each of the method steps is performed. Also, whenever the blood is perfused between the two sides of the balloon, any "treatment agent" delivered to the patient before this point will be in the blood stream (such as anesthesia) and will perfuse with the blood.

In reference to claim 62, Peacock discloses perfusing blood and treatment agent via a lumen extending through the cannula from a location proximal to the balloon to a location distal to the balloon, via a proximal hole through the exterior surface of the cannula and to the lumen at a location proximal to the balloon, and a distal hole through the exterior surface of the cannula and the lumen at a location distal to the balloon (Fig. 1a).

In reference to claim 63, Peacock discloses inflating the balloon for a first period of time to occlude the blood vessel for the first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing and deflating (paragraphs [0071]-[0073]).

In reference to claim 64, Peacock discloses retracting back a guidewire disposed through a guidewire lumen extending from the proximal end to the distal end of the cannula and exiting an opening in the cannula distal to a balloon, for a first period of time; wherein retracting includes retracting a distal end of the guidewire from a location distal to at least one hole from the guidewire lumen through the exterior surface of the cannula and proximal to the balloon to a location proximal to the at least one hole to cause perfusion through the at least one hole (paragraph [0099]).

In reference to claim 65, Peacock discloses advancing the guidewire to a location distal to the at least one hole to prohibit a blood and a treatment agent perfusion between a location in the blood vessel proximal to the balloon and the region of interest, for a second period of time, and repeating infusing, retracting and advancing at least one more (paragraph [0099]).

In reference to claim 66, Peacock discloses retracting a distal end of the guidewire to control an amount of a blood and a treatment agent perfusion between a location in the blood vessel proximal to the balloon and the region of interest by adjusting the guidewire to extend or retract a distal end of the guidewire to a location amongst a plurality of the at least one hole to allow a blood and a treatment agent to perfuse between the holes and the lumen at a selected perfusion rate (paragraph [0099]).

In reference to claim 68, Peacock discloses that inflating includes: increasing an axial length of the balloon; maintaining the inflation pressure on the inner diameter of the blood vessel (Fig. 1a).

In reference to claim 79, Peacock discloses perfusing the blood vessel coupled by human vasculature to a beating heart (paragraphs [0071]-[0073]).

In reference to claim 80, Peacock discloses perfusing the blood vessel in a person having a beating heart (paragraphs [0071]-[0073]).

In reference to claim 81, Peacock discloses perfusing blood via a lumen extending through the cannula from a location proximal to the balloon to a location distal to the balloon, via a proximal hole through the exterior surface of the cannula and to the lumen at a location proximal to the balloon, and a distal hole through the exterior surface of the cannula and to the lumen at a location distal to the balloon (Fig. 1a and paragraphs [0071]-[0073]).

In reference to claim 82, Peacock discloses perfusing blood flow from a location in the blood vessel proximal to the balloon, to a location in the region of interest distal to the balloon (Fig. 1a and paragraphs [0071]-[0073]).

In reference to claim 83, Peacock discloses retracting a distal end of the guidewire to the location proximal to the at least one hole proximal to the balloon, to allow the perfusion (paragraph [0099]).

In reference to claim 84, Peacock discloses perfusing blood or treatment agent (paragraphs [0071]-[0073]).

In reference to claim 85, Peacock discloses the method substantially as claimed except for the perfusing comprising perfusing the blood and treatment agent flow from the location in the blood vessel proximal to the balloon into the region of interest distal to the balloon. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the valve sequence of valves 6 and 7 in Fig. 1a to allow this to happen, especially since any treatment agent delivered to the patient before this operation is undertaken, such as the administration of anesthesia, will be found within the blood of the patient, and this treatment agent will perfuse with the blood.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peacock, III et al. (US 2002/0049402) in view of Alt (US Patent No. 6,805,860). Peacock discloses the method substantially as claimed except for the infusing of

progenitor cells. Alt, however, discloses a method of infusing progenitor cells (Fig. 1 and col. 13, lines 27-31). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Peacock with the step of infusing progenitor cells, as taught by Alt, in order to provide a method of treating a wider spectrum of diseases.

Response to Arguments

Applicant's arguments, see pages 6-8, filed 5/5/09, with respect to the rejection(s) of claim(s) 67 under Peacock as a 102 rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Peacock using the Peacock reference in an obviousness rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767